



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0085]

Draft Guidance on Classifying Significant Postmarket Drug Safety Issues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Classifying Significant Postmarket Drug Safety Issues.” This draft guidance describes FDA’s current approach to classifying a significant postmarket drug safety issue as a “priority” tracked safety issue (TSI) or a “standard” TSI, with the capability of elevating some priority TSIs to an “emergency” status. The draft guidance was developed in connection with the Center for Drug Evaluation and Research’s (CDER’s) Safety First Initiative.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Classifying Significant Postmarket Drug Safety Issues.” This draft guidance describes CDER’s current approach to determining whether a significant postmarket drug safety issue should be classified as a “priority,” as a “standard,” or as an “emergency” tracked safety issue (TSI).

CDER receives a constant flow of information about potential drug safety issues, and the seriousness of reported problems varies widely. Those that CDER determines to be significant safety issues are tracked in the Center’s Document Archiving, Reporting, and Regulatory Tracking System (DARRTS), a centralized data base that enables staff working across the Center

to share information. To be considered significant, the safety issue of concern must meet certain criteria. In general, CDER considers postmarket safety issues to be significant if they have the potential to lead to any of the following actions:

- Withdrawal of an approved drug from the market
- Withdrawal of an approved indication
- Limitations of a use in a specific population or subpopulation
- Additions or modifications to the Contraindications or Warnings and Precautions sections of the labeling, to the Medication Guide or other required Patient Package Insert, including safety labeling changes required under the Food and Drug Administration Amendments Act (FDAAA)
- Establishment of or changes to the proprietary name/container label/labeling/packaging to reduce the likelihood of medication errors
- Establishment or modification of a risk evaluation and mitigation strategy (REMS)
- A requirement that a sponsor conduct a safety-related postmarket clinical trial or observational epidemiological study
- The conduct of a safety-related observational epidemiological study by FDA.

Since the DARRTS safety tracking function was introduced in 2007, about 1,000 TSIs have been entered into the system. Although all of these issues are considered significant, not all TSIs are equally urgent. Furthermore, CDER does not have adequate resources to manage all TSIs equally rapidly. In the past, prioritization of the TSIs has been handled informally and on a case-by-case basis, without an agreed upon framework for establishing priority.

The Center is now seeking to establish a formal framework for assessing the relative urgency of TSIs, so that CDER can direct resources more effectively toward the issues that pose the greatest potential risk for patients. This framework will classify TSIs as “priority” or “standard” for CDER review. In addition, the Center will recognize a special “emergency” category for certain priority TSIs. The use of a formal framework is intended to ensure that staff working in different offices across CDER reaches similar conclusions about the relative urgency of TSIs, and help them direct attention to those that need to be addressed most expeditiously. It will also inform CDER decisions about public drug safety communications, so that health care practitioners and patients receive timely information about safety risks with the greatest public health significance.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

or <http://www.regulations.gov>.

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-5777 Filed 03/08/2012 at 8:45 am; Publication Date: 03/09/2012]